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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,004	02/09/2004	Stephen C. Wardlaw	5169-0003-1	2542

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EXAMINER

RAMILLANO, LORE JANET

ART UNIT	PAPER NUMBER
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1743

MAIL DATE	DELIVERY MODE
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10/03/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/775,004	Applicant(s) WARDLAW, STEPHEN C.	
	Examiner Lore Ramillano	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 March 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 13-19 is/are pending in the application.
- 4a) Of the above claim(s) 9-12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 13-19 is/are rejected.
- 7) ☒ Claim(s) 4 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/9/04 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>See Continuation Sheet</u> | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :2/9/04, 2/27/06, 5/8/06, and 3/13/07.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-8 and 13-19, drawn to a container for holding a biologic fluid sample for analysis, classified in class 422, subclass 102.
 - II. Claims 9-11, drawn to container for holding a biologic fluid sample for analysis comprising a fluid holding chamber that has at least a first through-plane thickness, classified in class 422, subclass 67.
 - III. Claim 12, drawn to a container for holding a biologic fluid sample for analysis comprising a first and second reagent, classified in class 422, subclass 57.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Groups I, II, and III are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed can have a materially different design, mode of operation, function, or effect because the Invention of Group I does not require a chamber that has at least a first through-plane thickness as recited in the Invention of Groups II and III; and the Invention of Group II does not require a plurality of reagents as recited in the Invention of Group III. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

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3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Richard D. Getz on 8/31/07 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-8 and 13-19.

Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

5. The information disclosure statements (IDS) submitted on 2/9/04, 2/27/06, 5/8/06, and 3/13/07 are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Priority

6. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/077214, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Here, the following subject matter in claims 1-8 and

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13-19 is not supported by the above provisional application: the mapped interior of the fluid holding chamber; the predetermined coordinate address of the feature within the fluid holding chamber; interior of the chamber is orthogonally mapped; and the geometric characteristics (i.e. step of known height, cavity of known height or volume, and a protuberance of known height or volume).

Claim Objections

7. Claim 4 is objected to because of the following informalities: claim 4 should depend on claim 1 because it does not appear to properly depend on claim 2. In addition, because claim 15, which recites similar subject matter, depends on independent claim 13, it would be more clear to have claim 4 depend on claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-8 and 13-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 13 are rejected because the language, "mapped interior" is not clear. Is the mapped interior a grid that is physically part of the fluid holding chamber?

Claims 1 and 13 are rejected because the language, "coordinate address" is not clear. Is the coordinate address a grid that is physically part of the fluid holding chamber?

Claim 2 is rejected because the language, "orthogonally mapped," is not clear.

Regarding claim 13, the word "means" is preceded by the word(s) "operable to" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

The term "known height or volume" in claims 5-8 and 16-19 is a relative term, which renders the claim indefinite. The term "known height of volume" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. **Claims 1-8 and 13-19** are rejected under 35 U.S.C. 102(b) as being anticipated by Nishimura et al. ("Nishimura" US 5427959).

Nishimura discloses a container for holding a biologic fluid sample for analysis, said container comprising: a fluid holding chamber having a first wall and a transparent second wall, and wherein the fluid holding chamber has a mapped interior so that positions within the fluid holding chamber are identifiable by a coordinate address; at least one feature or a means operable to enable a determination of the volume of a field of the fluid sample, the at least one feature located within the chamber at a predetermined coordinate address; and a label attached to

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said container, said label operable to supply the predetermined coordinate address within the fluid holding chamber (i.e. figs. 20-24, column 5, line 58 to column 7, line 2).

Nishimura further discloses the following: the interior of the chamber is orthogonally mapped; at least one feature operable to enable a determination of the volume of a field of the fluid sample includes a through-plane thickness, and the field of the fluid sample is located at the predetermined address; and at least one feature operable to enable a determination of the volume of a field of the fluid sample includes a geometric characteristic, which is a step of known height disposed in one or both of the first wall and second wall, a cavity of known height or volume disposed in one or both of the first wall and second wall, a protuberance of known height or volume disposed in one or both of the first wall and second wall, and an object of known volume (i.e. figs. 20-24, column 5, line 58 to column 7, line 2).

12. **Claims 1-8 and 13-19** are rejected under 35 U.S.C. 102(e) as being anticipated by Berndt (US 5781303).

Berndt discloses a container for holding a biologic fluid sample for analysis, said container comprising: a fluid holding chamber having a first wall and a transparent second wall, and wherein the fluid holding chamber has a mapped interior so that positions within the fluid holding chamber are identifiable by a coordinate address; at least one feature or a means operable to enable a determination of the volume of a field of the fluid sample, the at least one feature located within the chamber at a predetermined coordinate address; and a label attached to said container, said label operable to supply the predetermined coordinate address within the fluid holding chamber (i.e. figs. 1-5, column 2, line 50 to column 4, line 65).

Berndt further discloses the following: the interior of the chamber is orthogonally mapped; at least one feature operable to enable a determination of the volume of a

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field of the fluid sample includes a through-plane thickness, and the field of the fluid sample is located at the predetermined address; and at least one feature operable to enable a determination of the volume of a field of the fluid sample includes a geometric characteristic, which is a step of known height disposed in one or both of the first wall and second wall, a cavity of known height or volume disposed in one or both of the first wall and second wall, a protuberance of known height or volume disposed in one or both of the first wall and second wall, and an object of known volume (i.e. figs. 1-5, column 2, line 50 to column 4, line 65).

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. **Claims 1, 13, and 15** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 5 of U.S. Patent No. 6723290. Although the conflicting claims are not identical, they are not patentably distinct from each other because they both recite substantially the same subject matter.


Claims 1, 13, and 15 recite substantially the same subject matter as recited in the patent claim 5 – a chamber having a first wall and a transparent second wall; at least one feature operable to enable the analysis of the biologic fluid; wherein the at least one feature operable to enable said analysis includes one or more geometric characteristics.

Therefore, claims 1, 13, and 15 are fully encompassed by claim 5 of U.S. Patent No. 6723290.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lore Ramillano whose telephone number is (571) 272-7420. The examiner can normally be reached on Mon. to Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lore Ramillano
Examiner
Art Unit 1743


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